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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/695,116	10/24/2000	Vivek Thappa	THA-P-00-001	4881

7590 05/21/2003

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EXAMINER

GHAFOORIAN, ROZ

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 05/21/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/695,116

Applicant(s)

THAPPA, VIVEK

Examiner

Roz Ghafoorian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 October 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claims 1-26 are objected to because of the following informalities: in the independent claims 1,7 and 15 it is unclear if the applicant is claiming the catheter introducer or the catheter itself. Since the preamble of all independent claims refer to the "a catheter" and not a catheter introducer or assembly, the examiner is under the impression that the applicant is claiming the catheter assembly and therefore the preamble should read as such.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S Patent No.6059802 to Ginn, and further in view of U.S Patent No.5360414 to Yarger.

Ginn teaches a catheter introducer comprising of a cylindrical body defining a cross with a length deigned between a pointed end 26 and a flat end 30. A first part 24 and a second part 22, wherein the first and second part defines the cylindrical body. Locking mechanism figs 6-7 where the first part and the removable second part are locked

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together. The pointed end of the cylindrical body gradually tapers to the cylindrical portions. A recess portion 40 along the length of the first portion 22 and a protruding element 42 defined in shaped by a right angle located along the recessed portion of the first part. The recess portion 40 may readily accept the protrusion 42 along the length of the removable second part. A first hole 78 located a distance from the pointed end of the cylinder. A leg 66 attached to the bottom end of the cylinder. A second hole 70 located on the leg of the cylinder and a thread connected (locking mechanism) 80 and 74 to the cylinder form the second hole to the first hole. A groove or plurality of holes 38 cut into the cylinder. Ginn does not teach a catheter with two notches located a distance from each other.

Yarger teaches a catheter (tube) with two notches 28a distance from each other with a locking mechanism 24 located on the bottom end of the flexible body. The tube also comprises of multiple holes 28b.

Therefore it would have been obvious to one having ordinarily skill in the art to have used the catheter introducer of Ginn for the introduction of a catheter or tube such as Yarger, because its well known in the art that any tube or catheter needs an introducer for guidance and maneuvering into the body.

Allowable Subject Matter

2. Claims 15-20 allowed.

The following is a statement of reasons for the indication of allowable subject matter: the method of introducing a catheter via a catheter introducer where the introducer pierces the skin and the subcutaneous layer and the cylindrical body is

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pushed in and is exposed to an outside exit site of the body; and the second part of the cylinder of the introducer catheter is removed attaching a notch of the flexible hollow body of the catheter to the first part of the cylindrical body of the introducer catheter.

Response to Arguments

Applicant's arguments filed 3-17-2003 have been fully considered but they are not persuasive.

- a. The applicant alleges Ginn does not teach a flexible hollow body with a top end and a bottom end where the top end is closed and tapers to a cylindrical tube, furthermore the applicant claims Ginn does not teach a cylindrical body define a cross, a first part and a second part removalby attached. It's not clear how the applicant is defining or meaning by the word cross and due to lack of definition of cross in the specification the examiner has taken the dictionary definition of cross to mean to oppose, meaning to place against something. However as mentioned above Ginn teaches a catheter intorducer with cylinderial body 20 with a top end 26 and a bottom end 34, where the top end tapers to a cylindrical tube 27.
- b. The applicant alleges Ginn fails to teach a first part having a uniform width and a second section defining a cross wherein the first part and the second part define a cylindrical body. As mentioned above Ginn does teach a first part 24 a second part 28 where the second part define a cross (is placed against) first part forming a cylinder (figure 1)

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Conclusion

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Ghafoorian whose telephone number is 703-305-2336. The examiner can normally be reached on 8:30am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

RG
May 16, 2003

A handwritten signature in black ink, reading "Michael J. Hayes". The signature is written in a cursive, flowing style.

**MICHAEL J. HAYES
PRIMARY EXAMINER**